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EXAMINER	
NOGUEROLA, ALEXANDER STEPHAN	
ART UNIT	**PAPER NUMBER**
1753	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/020,776	Applicant(s) FRITSCH ET AL.	
	Examiner ALEX NOGUEROLA	Art Unit 1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28,32-43 and 46-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *32-43* is/are allowed.

6)☒ Claim(s) *1-28 and 46-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 October 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicants' amendment of October 28, 2005 ("Amendment") does not render the application allowable.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claim 1 has been amended to require that the analyte selective materials be suspended such that they do not come in contact with the submicroelectrodes. No support has been cited or found for this limitation. The original

disclosure, in fact, teaches away from such an arrangement as original Figures 17 and 18 show "[e]dges of bilayer anchored by alkanethiol-derivatized inner edges of AU layers." Replacement drawings 16-18 of the Amendment also show a bilayer membrane on a conducting surface.

Status of Objections and Rejections pending since the Office action of June 22, 2005

4. All previous rejections under 35 U.S.C. §103(a) are withdrawn.

5. The objection to the drawings is withdrawn.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 2-11, 13, 14, 16-24, 26, 46, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over the English language translation of Urban et al. (WO 90/12314 A1), hereafter "Urban," in view of Ufer (US 2003/0085124 A1), hereafter "Ufer," and Douglas et al. (US 2003/0106810 A1), hereafter "Douglas," Pace (US 4,225,410), hereafter ("Pace"), and Diebold et al. (US 5,437,999) ("Diebold"). It should be noted that although Ufer and Douglas do not have priority before Applicants' earliest

priority date of April 30, 1998, the examiner has not found support for a flexible polymer substrate in a microcavity device as claimed in any of Applicants' priority documents. Thus, until demonstrated otherwise, claims 2-25 will be accorded a priority date of December 12, 2001, which is the filing date of the instant application.

Addressing claim 2, Urban teaches a microcavity device comprising

(a) a substrate (element **5** in Figures 10-15);

(b) integrated, independently addressable electrodes (elements **1**, **2**, and **3** in Figures 10-15), wherein one of the electrodes is a disk electrode on the substrate and covering the bottom of the microcavity (Figures 10-13);

(c) conducting layers connected to the electrodes (not labeled but shown in or suggested by Figures 10-15), the conducting layers being planar and parallel to one another (inferred from Figures 9-15, which together show conducting layers extending from electrodes that are planar and parallel);

(d) an insulating layer separating adjacent conducting layers (element **4** in Figures 10-13);

(e) the conducting layers and the insulating layer being on top of the substrate (Figures 10-13); and

(f) at least one microcavity penetrating the conducing layers and the insulating layer, the microcavity having a depth, a diameter, and a top opening (Figures 10-13; the last full paragraph on page 15, claim 15, and the first full paragraph on page 18).

Urban does not mention using a flexible polymer substrate. Urban is in fact silent on possible substrate materials. However, Urban does disclose using polyimide insulator layers (last paragraph on page 17). Douglas and Ufer both teach microscale electrochemical sensor devices made of thin layers of insulating and conducting materials on a flexible substrate (the abstract; Figure 5; and paragraphs [0024] and [0026] in Douglas and the abstract; Figure 4; and paragraph [0027] and [0029] in Ufer). It would have been obvious to one with ordinary skill in the art at the time the invention was made to use a flexible substrate as taught by Douglas or Ufer in the invention of Urban because they each teach that a plurality of sensing device can then be made using continuous processing techniques (paragraph [0013] in Ufer and paragraph [0013] in Douglas), which, as taught by Douglas, "results in high volume manufacturing capability an [sic] substantial cost reductions over step and repeat processes." Also, Douglas and Ufer disclose polyimide as a possible flexible substrate material (paragraph 0021] in Douglas and paragraph [0022] in Ufer), which, as mentioned above, Urban discloses may be used for the insulating layers.

In the alternative, Ufer and Douglas are not needed to provide motivation for a flexible substrate because Urban already teaches insulating layers made from a flexible material (polyimide) and Urban teaches having the microcavity built into a catheter, which may be used for taking measurements in body cavities (page 12, first full paragraph and page 20, first full paragraph). In a catheter embodiment it would have been obvious to one with ordinary skill in the art at the time the invention was made to have the substrate be flexible so that the catheter

can be maneuvered in the patient's body with minimum discomfort and injury to the patient. More generally, if the sensor is to be inserted into a person it would have been obvious to one with ordinary skill in the art at the time of the invention to make the sensor flexible for the same reasons as for making a catheter embodiment flexible.

Urban also does not mention contact pads for the conducting layers. Pace discloses an integrated array of electrochemical sensors each sensor having a cavity and planar, parallel electrodes with conducting layers and contact pads. See the abstract and Figures 3, 4, and 6. Diebold discloses an electrochemical sensor having spaced planar, parallel electrodes with conducting layers and contact pads. See the abstract and Figures 5 and 6. It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide contact pads as taught by Urban and Diebold in the invention of Urban as modified by Ufer and Douglas because it would then be more convenient to make measurements. Sample need only applied to the small easily held sensor rather than a large bulky meter with power source and display. Also, since the sample is only applied to the sensor contamination of the meter is avoided as only the contact pads contact the meter. Furthermore, the meter can be used for sensors that are configured for different analyses. One sensor may measure glucose and fructose and another sensor may measure cholesterol and lactose, for example.

Urban also does not mention *not* using the disk electrode at the bottom of the microcavity as a reference electrode; however, this limitation is only intended use that does not further structurally distinguish the claimed invention from that of Urban as

modified by Ufer, Pace, Douglas, and Diebold. Urban discloses that all of the electrodes in the microcavity may have the same composition. See in Urban the second full paragraph on page 18 and claim 13. Thus, barring a contrary showing, whether an electrode in Urban is used as a reference electrode may just depend on the potential applied to it.

Addressing claims 3 and 17, Urban discloses having a membrane over the electrodes (second paragraph on page 11 and claim 12). From Figures 10-13 one with ordinary skill in the art at the time of the invention would have envisaged the membrane as covering the top opening. Indeed, for the embodiments in Figures 10 and 12 the membrane must cover the top opening if it is also to cover all of the electrodes.

Addressing claims 4, 5, and 18, the membrane is for "selective acquisition of certain electroactive species" (page 11, second paragraph of Urban). That is, the membrane is selectively permeable. One with ordinary skill in the art at the time of the invention would have understood that the membrane is to be permeable to analytes of interest and necessary or useful electrolytes.

Addressing claims 6, 7, 10, 19, 20, and 23 although no specific dimensions are mentioned by Urban, barring evidence to the contrary, such as unexpected results, the dimensions claimed by Applicants are just a matter of scaling the device of Urban as modified by Ufer and Douglas to best accommodate the expected sample volume

because Urban clearly teaches micro and submicron scale dimensions and measuring very small analyte concentrations (second paragraph on page 3; page 5, sixth line form the bottom to last line on page 6; claims 1 and 15; and next to last paragraphs on pages 7 and 15).

Addressing claims 8 and 21, Urban discloses band and disc electrodes (electrode **1** is a disc electrode, and electrodes **2** and **3** are band electrodes. See Figures 13 and 14, for example).

Addressing claims 9 and 22, Urban discloses at least two electrodes in the cavity (Figures 10-15).

Addressing claims 11, 13, and 24, Urban discloses providing a plurality of microcavities (Figures 14 and 15), each microcavity being a complete electrochemical cell (each microcavity comprises a measurement electrode (2), a counterelectrode (3), and a reference
electrode (1)).

Addressing claims 14 and 26, that the device is a recessed disk microelectrode may be seen form Figures 10-13.

Addressing claim 16, Urban teaches a microcavity device comprising

(a) a substrate (element **5** in Figures 10-15);

(b) integrated, independently addressable electrodes (elements **1**, **2**, and **3** in Figures 10-15);

(c) conducting layers connected to the electrodes (not labeled but shown in or suggested by Figures 10-15), the conducting layers being planar and parallel to one another (inferred from Figures 9-15, which together show conducting layers extending from electrodes that are planar and parallel), wherein one of the electrodes is a microdisk electrode on the substrate and covering the bottom of the microcavity (Figures 10-13);

(d) an insulating layer separating adjacent conducting layers (element **4** in Figures 10-13);

(e) the conducting layers and the insulating layer being on top of the substrate (Figures 10-13); and

(f) at least one microcavity penetrating the conducing layers and the insulating layer, the microcavity having a depth, a diameter, and a top opening (Figures 10-13; the last full paragraph on page 15, claim 15, and the first full paragraph on page 18);

(g) wherein the microcavity is a self-contained electrochemical cell (each microcavity comprises a measurement electrode (2), a counterelectrode (3), and a reference

electrode (1). See second full paragraph on page 14); and

(h) a device for measuring electrical potential difference or current between electrodes (Urban discloses at least making potentiodynamic measurements (last line on page 6 bridging to page 7).

Urban does not mention using a flexible polymer substrate. Urban is in fact silent on possible substrate materials. However, Urban does disclose using polyimide insulator layers (last paragraph on page 17). Douglas and Ufer both teach microscale electrochemical sensor devices made of thin layers of insulating and conducting materials on a flexible substrate (the abstract; Figure 5; and paragraphs [0024] and [0026] in Douglas and the abstract; Figure 4; and paragraph [0027] and [0029] in Ufer). It would have been obvious to one with ordinary skill in the art at the time the invention was made to use a flexible substrate as taught by Douglas or Ufer in the invention of Urban because they each teach that a plurality of sensing device can then be made using continuous processing techniques (paragraph [0013] in Ufer and paragraph [0013] in Douglas), which as taught by Douglas "results in high volume manufacturing capability an [sic] substantial cost reductions over step and repeat processes." Also, Douglas and Ufer disclose polyimide as a possible flexible substrate material (paragraph 0021] in Douglas and paragraph [0022] in Ufer), which, as mentioned above, Urban discloses may be used for the insulating layers.

In the alternative, Ufer and Douglas are not needed to provide motivation for a flexible substrate because Urban already teaches insulating layers made from a flexible material (polyimide) and Urban teaches having the microcavity built into a catheter, which may be used

for taking measurements in body cavities (page 12, first full paragraph and page 20, first full paragraph). In a catheter embodiment it would have been obvious to one with ordinary skill in the art at the time the invention was made to have the substrate be flexible so that the catheter can be maneuvered in the patient's body with minimum discomfort and injury to the patient.

Urban also does not mention contact pads for the conducting layers. Pace discloses an integrated array of electrochemical sensors each sensor having a cavity and planar, parallel electrodes with conducting layers and contact pads. See the abstract and Figures 3, 4, and 6. Diebold discloses an electrochemical sensor having spaced planar, parallel electrodes with conducting layers and contact pads. See the abstract and Figures 5 and 6. It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide contact pads as taught by Urban and Diebold in the invention of Urban as modified by Ufer and Douglas because it would then be more convenient to make measurements. Sample need only applied to the small easily held sensor rather than a large bulky meter with power source and display. Also, since the sample is only applied to the sensor contamination of the meter is avoided as only the contact pads contact the meter. Furthermore, the meter can be used for sensors that are configured for different analyses. One sensor may measure glucose and fructose and another sensor may measure cholesterol and lactose, for example.

Urban also does not mention *not* using the disk electrode at the bottom of the microcavity as a reference electrode; however, this limitation is only intended use that does not further structurally distinguish the claimed invention from that of Urban as modified by Ufer, Pace, Douglas, and Diebold. Urban discloses that all of the electrodes in the microcavity may have the same composition. See in Urban the

second full paragraph on page 18 and claim 13. Thus, barring a contrary showing, whether an electrode in Urban is used as a reference electrode may just depend on the potential applied to it.

Addressing claims 46 and 48, Urban as modified by Ufer, Douglas, Pace, and Diebold does not mention providing an adhesion layer between the insulating and conducting layers and the conducting layer and the substrate. Diebold discloses providing an adhesion layer between a conducting layer and a non-conducting layer. See col. 3:50-65. It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide an adhesion layer as taught by Diebold in the invention of Urban as modified by Ufer, Douglas, Pace, and Diebold because as taught by Diebold, the adhesion layer will increase adhesion between the conducting material and the support material, as well as stabilize the microstructure of conducing material. See col. 3:62-65.

10. Claims 12 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Urban in view of Ufer, Douglas, Pace, and Diebold as applied to claims 2-11 13, 14, 16-24, 26, 46, 48 above, and further in view of Wolf et al. (US 6,376,233 B1), hereafter "Wolf."

Urban does not mention including at least 96 wells in the microcavity device, although as noted in the rejection of claim 11 Urban does disclose a plurality of wells. Wolf discloses a microtiter plate having 96 wells with a sensor, which may be an electrode-based sensor, in each well (abstract; Figures 3 and 4; col. 2, ll. 46-53; and claim 12). Barring evidence to the contrary, such as unexpected results, to provide 96 wells as taught by Wolf in the invention of Urban as modified by Ufer and Douglas (or just Urban if the alternative motivation of claims 2 and 16 is used) is just further multiplication of parts for a multiplied effect, which is in itself obvious. It would have been obvious to one with ordinary skill in the art at the time the invention was made to proved at least 96 sensor wells as taught by Wolf in the invention of Urban as modified by Ufer and Douglas (or just Urban if the alternative motivation of claims 2 and 16 is used) so that many samples can be simultaneously and independently analyzed.

11. Claims 15, 27, 47, and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over the English language translation of Urban et al. (WO 90/12314 A1), hereafter "Urban," in view of Pace (US 4,225,410), hereafter ("Pace"), and Diebold et al. (US 5,437,999) ("Diebold").

Addressing claim 15, Urban teaches a microcavity device comprising

(a) a silicon substrate (element **5** in Figures 10-15; Urban discloses silicon insulating layers (first full paragraph on page 18);

(b) integrated, independently addressable electrodes (elements **1**, **2**, and **3** in Figures 10-15), wherein one of the electrodes is a microdisk electrode on the substrate and covering the bottom of the microcavity (Figures 10-13);

(c) conducting layers connected to the electrodes (not labeled but shown in or suggested by Figures 10-15), the conducting layers being planar and parallel to one another (inferred from Figures 9-15, which together show conducting layers extending from electrodes that are planar and parallel);

(d) an insulating layer separating adjacent conducting layers (element **4** in Figures 10-13);

(e) the conducting layers and the insulating layer being on top of the substrate (Figures 10-13); and

(f) at least one microcavity penetrating the conducing layers and the insulating layer, the microcavity having a depth, a diameter, and a top opening (Figures 10-13; the last full paragraph on page 15, claim 15, and the first full paragraph on page 18).

As noted above, Urban discloses silicon insulating layers (first full paragraph on page 18). It would have been obvious to one with ordinary skill in the art at the time the invention was made to also have the substrate made of silicon because this would simplify the manufacturing process as the substrate is essentially just another insulating layer, except, perhaps, thicker.

Urban also does not mention contact pads for the conducting layers. Pace discloses an integrated array of electrochemical sensors each sensor having a cavity

and planar, parallel electrodes with conducting layers and contact pads. See the abstract and Figures 3, 4, and 6. Diebold discloses an electrochemical sensor having spaced planar, parallel electrodes with conducting layers and contact pads. See the abstract and Figures 5 and 6. It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide contact pads as taught by Urban and Diebold in the invention of Urban as modified by Ufer and Douglas because it would then be more convenient to make measurements. Sample need only applied to the small easily held sensor rather than a large bulky meter with power source and display. Also, since the sample is only applied to the sensor contamination of the meter is avoided as only the contact pads contact the meter. Furthermore, the meter can be used for sensors that are configured for different analyses. One sensor may measure glucose and fructose and another sensor may measure cholesterol and lactose, for example.

Urban also does not mention *not* using the disk electrode at the bottom of the microcavity as a reference electrode; however, this limitation is only intended use that does not further structurally distinguish the claimed invention from that of Urban as modified by Ufer, Pace, Douglas, and Diebold. Urban discloses that all of the electrodes in the microcavity may have the same composition. See in Urban the second full paragraph on page 18 and claim 13. Thus, barring a contrary showing, whether an electrode in Urban is used as a reference electrode may just depend on the potential applied to it.

Addressing claim 27, Urban teaches a microcavity device comprising

(a) a silicon substrate (element **5** in Figures 10-15; Urban discloses silicon insulating layers (first full paragraph on page 18);

(b) integrated, independently addressable electrodes (elements **1**, **2**, and **3** in Figures 10-15), wherein one of the electrodes is a microdisk electrodes on the substrate and covering the bottom of the microcavity (Figures 10-13);

(c) conducting layers connected to the electrodes (not labeled but shown in or suggested by Figures 10-15), the conducting layers being planar and parallel to one another (inferred from Figures 9-15, which together show conducting layers extending from electrodes that are planar and parallel);

(d) an insulating layer separating adjacent conducting layers (element **4** in Figures 10-13);

(e) the conducting layers and the insulating layer being on top of the substrate (Figures 10-13); and

(f) at least one microcavity penetrating the conducing layers and the insulating layer, the microcavity having a depth, a diameter, and a top opening (Figures 10-13; the last full paragraph on page 15, claim 15, and the first full paragraph on page 18);

(g) wherein the microcavity is a self-contained electrochemical cell (each microcavity comprises a measurement electrode (2), a counterelectrode (3), and a reference

electrode (1). See second full paragraph on page 14); and

(h) a device for measuring electrical potential difference or current between electrodes (Urban discloses at least making potentiodynamic measurements (last line on page 6 bridging to page 7).

As noted above, Urban discloses silicon insulating layers (first full paragraph on page 18). It would have been obvious to one with ordinary skill in the art at the time the invention was made to also have the substrate made of silicon because this would simplify the manufacturing process as the substrate is essentially just another insulating layer, except, perhaps, thicker.

Urban also does not mention contact pads for the conducting layers. Pace discloses an integrated array of electrochemical sensors each sensor having a cavity and planar, parallel electrodes with conducting layers and contact pads. See the abstract and Figures 3, 4, and 6. Diebold discloses an electrochemical sensor having spaced planar, parallel electrodes with conducting layers and contact pads. See the abstract and Figures 5 and 6. It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide contact pads as taught by Urban and Diebold in the invention of Urban as modified by Ufer and Douglas because it would then be more convenient to make measurements. Sample need only applied to the small easily held sensor rather than a large bulky meter with power source and display. Also, since the sample is only applied to the sensor contamination of the meter is avoided as only the contact pads contact the meter. Furthermore, the meter can be used for sensors that are configured for different analyses. One sensor may measure

glucose and fructose and another sensor may measure cholesterol and lactose, for example.

Urban also does not mention *not* using the disk electrode at the bottom of the microcavity as a reference electrode; however, this limitation is only intended use that does not further structurally distinguish the claimed invention from that of Urban as modified by Ufer, Pace, Douglas, and Diebold. Urban discloses that all of the electrodes in the microcavity may have the same composition. See in Urban the second full paragraph on page 18 and claim 13. Thus, barring a contrary showing, whether an electrode in Urban is used as a reference electrode may just depend on the potential applied to it.

Addressing claims 47 and 49, Urban as modified by Pace and Diebold does not mention providing an adhesion layer between the insulating and conducting layers and the conducting layer and the substrate. Diebold discloses providing an adhesion layer between a conducting layer and a non-conducting layer. See col. 3:50-65. It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide an adhesion layer as taught by Diebold in the invention of Urban as modified by Ufer, Douglas, Pace, and Diebold because as taught by Diebold, the adhesion layer will increase adhesion between the conducting material and the support material, as well as stabilize the microstructure of conducing material. See col. 3:62-65.

12. Claims 28 and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by the English language translation of Urban et al. (WO 90/12314 A1), hereafter "Urban."

Addressing claim 28, Urban teaches a microcavity device comprising

(a) a substrate (element **5** in Figures 10-15);

(b) integrated, independently addressable electrodes (elements **1**, **2**, and **3** in Figures 10-15);

(c) conducting layers connected to the electrodes (not labeled but shown in or suggested by Figures 10-15), the conducting layers being planar and parallel to one another (inferred from Figures 9-15, which together show conducting layers extending from electrodes that are planar and parallel);

(d) an insulating layer separating adjacent conducting layers (element **4** in Figures 10-13);

(e) the conducting layers and the insulating layer[s] being on top of the substrate (Figures 10-13);

(f) at least one microcavity penetrating the conducing layers and the insulating layer[s], the microcavity having a depth, a bottom, a diameter, and a top opening (Figures 10-13; the last full paragraph on page 15, claim 15, and the first full paragraph on page 18); and

(g) wherein the disk electrode is recessed from the main plane of an insulating layer of the substrate.

Urban also does not mention contact pads for the conducting layers. Pace discloses an integrated array of electrochemical sensors each sensor having a cavity

and planar, parallel electrodes with conducting layers and contact pads. See the abstract and Figures 3, 4, and 6. Diebold discloses an electrochemical sensor having spaced planar, parallel electrodes with conducting layers and contact pads. See the abstract and Figures 5 and 6. It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide contact pads as taught by Urban and Diebold in the invention of Urban as modified by Ufer and Douglas because it would then be more convenient to make measurements. Sample need only applied to the small easily held sensor rather than a large bulky meter with power source and display. Also, since the sample is only applied to the sensor contamination of the meter is avoided as only the contact pads contact the meter. Furthermore, the meter can be used for sensors that are configured for different analyses. One sensor may measure glucose and fructose and another sensor may measure cholesterol and lactose, for example.

The disk electrodes in Urban do not cover the entire bottom of the microcavity. However, barring a showing to the contrary this just a matter of desired dimensions for the overall dimensions of the sensor and its microcavites. For example, in the embodiment of Figure 11 of Urban if the microcavity is made the same width as that of the disk electrode (1) then the disk electrode will cover the entire bottom of the microcavity; however, the depth of the microcavity and thus the sensor thickness will have to be increased so that it can accommodate the same sample volume as t did before the microcavity width was narrowed.

Urban also does not mention *not* using the disk electrode at the bottom of the microcavity as a reference electrode; however, this limitation is only intended use that does not further structurally distinguish the claimed invention from that of Urban as modified by Ufer, Pace, Douglas, and Diebold. Urban discloses that all of the electrodes in the microcavity may have the same composition. See in Urban the second full paragraph on page 18 and claim 13. Thus, barring a contrary showing, whether an electrode in Urban is used as a reference electrode may just depend on the potential applied to it.

Addressing claim 50, Urban as modified by Ufer, Douglas, Pace, and Diebold does not mention providing an adhesion layer between the insulating and conducting layers and the conducting layer and the substrate. Diebold discloses providing an adhesion layer between a conducting layer and a non-conducting layer. See col. 3:50-65. It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide an adhesion layer as taught by Diebold in the invention of Urban as modified by Ufer, Douglas, Pace, and Diebold because as taught by Diebold, the adhesion layer will increase adhesion between the conducting material and the support material, as well as stabilize the microstructure of conducing material. See col. 3:62-65.

Drawings

13. Replacement drawings 17 and 18 appear to show lipid bilayer 160 on an insulating layer. However, original Figures 17 and 18 appear to show lipid bilayer 160 attached at its ends to a conducting layer. As disused in the rejection under 35 U.S.C. §112, first paragraph, above Applicants do not appear to have support in the original disclosure for analyte selective organic materials being suspend such that they do not come in contact with the submicroelectrodes. Thus, Figures 17 and 18 are objected to because they appear to introduce new matter.

Allowable Subject Matter

14. Claims 32-43 are allowed.

15. Claim 32: the nonobvious limitation in the combination of limitations is the requirement that the microelectrode comprise a silicon wafer to act as a substrate and polyimide insulating layers to separate the conducting.

Urban is silent on possible materials for the substrate other than indicating that it be inert (last paragraph on page 14, for example). Urban does disclose an embodiment having one or more silicon layers. However, in this embodiment the silicon layers are insulation layers (first full paragraph on page 18). Urban also

indirectly discloses polyimide as an alternative to silicon for use in forming insulating layers because Urban discloses that if polyimide insulating layers are used then deep microcavities may be formed (last paragraph on page 17 bridging to page 18). In light of these disclosures of Urban one would either use silicon for the substrate and the insulating layers or polyimide for the substrate and the insulating layers.

d) Claims 33-43 depend directly or indirectly from allowable claim 32.

Final Rejection

16. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alex Noguerola
Alex Noguerola
Primary Examiner
AU 1753
December 30, 2005